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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/092,546	06/05/1998	BEAT KINDLER	6348	6213

25763 7590 11/02/2005

DORSEY & WHITNEY LLP  
INTELLECTUAL PROPERTY DEPARTMENT  
50 SOUTH SIXTH STREET  
MINNEAPOLIS, MN 55402-1498

EXAMINER
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DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/092,546

Applicant(s)

KINDLER ET AL.

Examiner

Matthew F. DeSanto

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 9/27/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,6-9,15-18,20,21,26,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-9,15-18,20,21,26,37 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/27/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 6-9, 15-18, 20-21, 26, 37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (USPN 3759425).

Lee discloses a device for metered administering fluid of a fluid comprising a container having a piston through an outlet, a catheter connected to the outlet to the container having a front end and will inherently contain an injection needle. He teaches a valve having an inlet and an outlet and injection needle that can be attached to the distal end, the valve having an inlet and outlet end wherein flow of fluid is permitted from the outlet to the injection needle when pressure is exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the pressure of the fluid drug. (Figures 1-8, and entire reference)

3. Claims 1, 2, 6-9, 15, 16, 17, 26, 37, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Caldwell et al. (USPN 4,935,009).

Caldwell et al. discloses a device for metered administering fluid of a fluid comprising a container having a piston through an outlet, a catheter connected to the outlet to the container having a front end and will inherently contain an injection needle. He teaches a valve having an inlet and an outlet and injection needle that can be

attached to the distal end, the valve having an inlet and outlet end wherein flow of fluid is permitted from the outlet to the injection needle when pressure is exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the pressure of the fluid drug. (Figures 2, 2B, 4-6, and entire reference)

4. Claims 1, 2, 6-9, 15, 16, 17, 18, 20, 26, 37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Winnard (USPN 3,601,151).

Winnard discloses a device for metered administering fluid of a fluid comprising a container having a piston through an outlet, a catheter connected to the outlet to the container having a front end and will inherently contain an injection needle. He teaches a valve having an inlet and an outlet and injection needle that can be attached to the distal end, the valve having an inlet and outlet end wherein flow of fluid is permitted from the outlet to the injection needle when pressure is exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the pressure of the fluid drug. (Figures 1, 4, and entire reference)

5. Claims 1, 2, 6-9, 15, 26, 37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Cardenas (USPN 5616133).

Cardenas discloses a device for metered administering fluid of a fluid comprising a container having a piston through an outlet, a catheter connected to the outlet to the container having a front end and will inherently contain an injection needle. He teaches a valve having an inlet and an outlet and injection needle that can be attached to the distal end, the valve having an inlet and outlet end wherein flow of fluid is permitted from the outlet to the injection needle when pressure is exerted on the inlet end of the valve

exceeds a pressure on the inlet end caused by the pressure of the fluid drug. (Figures 1-4, 12, and entire reference)

### ***Response to Arguments***

6. Applicant's arguments filed 9/27/04 have been fully considered and are not persuasive

7. The applicant argues Lee doesn't include a fluid column and an ampoule or container that contains fluid. The examiner disagrees with these statements because Lee shows a fluid column in figures 3 and 7. With regards to the ampoule, the examiner uses the ordinary definition, which is a sealed vessel to hold fluid for injection. The prior art of record teaches this, since all the reference are syringes and are capable of having fluid in the container, especially if the syringe is being used to inject fluid into the body. This is true for all the prior art (Caldwell, Winnard, and Cardenas). The examiner would also like to note, that since the syringe of the prior art doesn't dip fluid when fluid is in the container or ampoule, there must be a certain cracking pressure of the valve to ensure the fluid doesn't freely escape the syringe, and therefore meeting the limitations of the claimed invention. Each prior art device has a valve and each valve has a cracking pressure, thus each valve will fulfill the requirements of the claim limitations.

### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3763


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Matthew DeSanto  
Art Unit 3763  
September 19, 2005



NICHOLAS D. LUCCHESI  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700